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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,689	09/19/2003	James Lee	P0706P2C2D2C1	2217

9157 7590 07/14/2006

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EXAMINER	
ULM, JOHN D	

ART UNIT	PAPER NUMBER
1649	

DATE MAILED: 07/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/666,689	LEE ET AL.	
	Examiner	Art Unit	
	John D. Ulm	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 April 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-73* is/are pending in the application.

4a) Of the above claim(s) *31-73* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/14/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1) Claims 20 to 73 are pending in the instant application. Claims 25 and 27 have been amended as requested by Applicant in the correspondence filed 14 April of 2006.

2) Any objection or rejection of record that is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

3) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4) Claims 31 to 73 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the correspondence filed 15 August of 2005.

5) Claims 20 to 30 stand rejected under 35 U.S.C. § 101 because they are drawn to an invention with no apparent or disclosed specific and substantial credible utility for those reasons of record in section 3 of the office action mailed 14 October of 2005. As stated therein, the instant claims are drawn to an isolated "PF4AR" protein that lacks a specific and substantial utility in currently available form because the instant application does not disclose a specific biological role for this protein or its significance to a particular disease, disorder of physiological process which one would wish to manipulate for a desired clinical effect.

Applicant has traversed this rejection essentially on the basis that, because the amino acid sequence presented in SEQ IED NO:6 of the instant application is sufficiently similar to known chemokine receptors, being "36% and 38% identical with

the high and low affinity IL-8 receptor sequences, respectively", as disclosed in lines 22 and 23 on page 55 of the instant specification, and because agonist activation of chemokine receptors in general induces an inflammatory response, antagonistic antibodies to the claimed protein would be expected to be anti-inflammatory. None of this reasoning is disputed, even though it is noted that there is no experimental evidence that the agonist activation of the claimed protein actually induces an inflammatory response.

However, it is a matter of law that an invention must have a specific and substantial utility "in currently available form", which precludes the need for further research, if that research is needed to establish or reasonably confirm a utility for the claimed invention (*Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966)). The Chuntharapai et al. publication (METHODS IN ENZYMOLOGY 288:15-27, 1997) describes the state of the art at the time of the instant invention with respect to the generation of antagonistic (blocking) antibodies to members of the chemokine receptor family. As shown by Table 1 on page 23 of that reference, not every antibody that binds to the ligand-binding domain of a chemokine receptor is an antagonistic antibody. As stated in the second full paragraph on page 22 of Chuntharapai et al., "[o]ne can select antagonistic Mabs to a particular receptor by determining their abilities to inhibit bioactivities of the relevant ligand". The claimed protein lacks specific and substantial utility **in currently available form** because, before one can employ that protein in the identification of antagonistic antibodies thereto, one must first discover the identity of a native agonist for that protein. Further, before the claimed protein has substantial utility

in the production of anti-inflammatory antibodies, one must first identify a native agonist thereto **and confirm** that the agonist activation of the claimed protein actually mediates an inflammatory response.

Applicant's assertion that a polypeptide of the instant invention can be used as a proinflammatory agent is not believable on its face. Nothing in the evidence or art of record supports a conclusion that the administration of any member of the G protein-coupled receptor family will have any effect what so ever on an inflammatory response by an animal to which it has been administered. There is not a single reference of record, published before or after the filing of the instant application that describes the successful exogenous administration of a G protein-coupled receptor, or portion thereof, for the purpose of achieving a clinical effect. At best, the evidence of record supports the conclusion that a **native agonist** for the claimed protein **may** be proinflammatory. But the instant claims are not drawn to such an agonist and the instant specification does not describe even a single working example of an agonist for the claimed protein.

The declaration by James Lee under 37 CFR 1.132 filed 14 April of 2006 is insufficient to overcome the rejection of claims 20 to 30 based upon a lack of specific and substantial utility as set forth in the last Office action because it does not address the issue of the additional experimentation and acts of discovery that are required before the claimed protein can be employed in a practical application.

The declarant relies upon the Stoeckle et al. and Miller et al. publication to "verify that the state of the art at the time of filing recognized that CXC chemokines played important roles in regulating inflammation" and that "Stoeckle et al. also recognizes that

the inhibition of CXC chemokine activity may be an effective anti-inflammatory therapeutic strategy". This is not disputed. However, as explained above, the instant application fails to disclose the identity of a specific chemokine that regulates inflammation by acting upon a protein of the instant invention. Therefore, one can not identify an inhibitor of that chemokine until one first discovers its identity, and this additional inventive contribution is required before the claimed protein has specific utility in currently available form.

6) Claims 20 to 30 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to use the instant invention for those reasons given above with regard to the rejection of these claims under 35 U.S.C. § 101.

7) Claims 20 to 30 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for those reasons of record in section 5 of the office action mailed 14 October of 2005. As stated therein, these claims are vague and indefinite in so far as they employ the term "PF4AR" as a limitation. Applicant urges that this term is not intended to materially limit the claimed subject matter. Therefore, Applicant should not object to removing this limitation since an artisan can not determine if a compound which meets all of the other limitations of a claim would then be included or excluded from the claimed subject matter by the presence of this limitation. For example, it is unclear how the limitation "the amino acid sequence of Figure 5" differs in scope from "the PF4AR amino acid sequence of Figure 5". Whereas an Artisan could readily determine the metes and bounds of the first

limitation, that artisan can not determine what additional material is encompassed or excluded by the presence of the term "PF4AR".

8) Claims 25 and 27 are vague and indefinite because the metes and bounds of the limitation "extracellular segment" are unclear. Applicant has identified the text in lines 15 to 19 on page 5 and lines 13 to 25 on page 15 of the instant specification as defining these terms. Applicant urges that this term is "being specifically defined by the recited residues and comprising more than one amino acid residue". This is not persuasive because, first, the limitation "extracellular segment" appears nowhere on page 15 of the instant specification. Second, the definition of this term that is provided on page 5 is vague because it employs the term "approximately delineated" to identify amino acid residues that define the boundaries of the segments described therein. This is particularly confusing because each of the range values recited therein are greater than 10 amino acids in length and yet, dependant claims supposedly further limit claims 25 and 27, respectively, to segments that are at least 10 amino acids in length. Therefore, it is clearly not Applicant's intention that an extracellular segment be limited in length to no less that the amino acid residues identified in lines 17 and 18 on page 5 of the instant specification. Claims 26, 28 and 30 are vague and indefinite in so far as they depend from either or both of claims 25 and 27 for this element.

9) Claims 26 and 28 are vague and indefinite because there is no antecedent basis for "the extracellular region".

10) Applicant's arguments filed 14 April of 2006 have been fully considered but they are not persuasive.

11) Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12) This application contains claims 31 to 73, drawn to an invention nonelected with traverse in the correspondence filed 15 August of 2005. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (571) 272-0880. The examiner can normally be reached on 9:00AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JOHN ULM
PRIMARY EXAMINER
GROUP 1800